Ubrolexin

intramammary suspension for lactating dairy cows

PHARMACEUTICAL FORM

Intramammary suspension Off-white sterile, oily paste.

COMPOSITION

Each 10 g (12 ml) intramammary syringe contains:

Cefalexin (as monohydrate): 200 mg Kanamycin (as monosulphate): 100,000 I.U.

Target species

Cattle (lactating dairy cows)

Indications for use

Treatment of clinical mastitis in lactating dairy cows for bacteria susceptible to the combination of cefalexin and kanamycin such as *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Escherichia coli* and coagulase-negative staphylococci.

Dosage routes and method of administration

For intramammary use only.

Treat the infected quarter(s) of the udder twice in an interval of 24 hours.

Use the contents of one syringe per quarter per treatment.

Each syringe is for single use only. Before infusion the udder should be milked out completely, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle.

Contraindications

Do not use in lactating dairy cows with a known hypersensitivity to cefalexin and/or kanamycin. Do not use in non-lactating cattle.

Do not use where resistance is known to occur.

Adverse reactions

None known

Withdrawal periods

Meat and offal: 10 days

Milk: 5 days

Special precautions for use in animals:

Recommendations for prudent use

The product should be used for treatment of clinical mastitis, only.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional and farm level) epidemiological information about susceptibility of the target bacteria as well as by taking into account official national antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to cefalexin and kanamycin and may decrease the effectiveness of treatment with other cephalosporins or aminoglycosides due to the potential for cross-resistance.

Use during pregnancy and lactation:

The product can be used in pregnant cows. The product is intended for use during lactation.

Interaction with other medicinal products and other forms of interaction

In case of resistance to cefalexin, cross-resistance with other cephalosporins is likely to occur. In case of resistance to kanamycin, cross-resistance occurs between kanamycin, neomycin and paromomycin. A one way resistance with streptomycin is known.

Manufacturer:

Univet Ltd., Ireland.

Marketing Authorization Holder:

Boehringer Ingelheim, Germany.